

PATIENT S

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Abstract

Hospital acquired infections and the complications associated with this are an increasing problem worldwide. New techniques and tools are needed to reduce the risk to acquire infection during hospitalisation. The present device has been designed with an aim to obtain a process in connection to surgery that provides a comprehensive and comfortable sterilization of the patient.

The actual bactericidal effect is based on a relatively new technique – non-thermal plasma. The technique has been tested in laboratory settings with very promising effects on various bacteria.

The design of the device has been focused on ergonomics, simpleness and reliability. The special regulatory requirements for medical devices have also been considered.

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Introduction

Background

The field of healthcare is a well-debated sector in the society primarily with regard to health-related problems but also to cost effectiveness. It is also a field that historically has been more affected by functionalism than any other design. Because of this it is interesting to segment the general processes, to see what is possible to develop.

Hospital-acquired infections are a major problem in today's healthcare. Hospital-associated infections are the infections not incubating at the time the patients admit to the hospital. In Sweden only, 9.3%[1] of the patients are infected during hospitalisation. Worldwide the problem is enormous. Infections may lead to long hospitalizations and even deaths.

Risk factors for new infections[2]

- Older patients that are more likely to pick up infections
- Complex equipment, that is difficult to clean
- Patients who are susceptible to some types of infections is brought together in larger groups
- High turnovers in staff, which makes it difficult to keep a uniformed standard
- New effective sterilization systems that not yet is understood by the staff and the concerned

Problem formulation

In defining the project further, limitations were made to the sterilisation process that is performed in connection to a surgical intervention. A process comprising several sterilization steps, from where the patients sterilize themselves at home to the sterilization at the hospital by the hospital personnel.

The question that arose from this was if the patient's knowledge and behaviour was enough and if the home sterilisation could be considered adequate as a full-body sterilisation? Does the patient comply with the given instructions?

The purpose of this project was to find a better way to manage the disinfection of patients before surgery, and that idea was to be developed into a conceptual product.

From a long-term perspective, the idea of this product was to shorten the overall time in hospital stays, to minimize physical and mental damage to patients, reduce the costs involved and above all to reduce the number of deaths associated to infections.

In line with this I wanted to evaluate the possibility of new sterilisation techniques that could be used in the surgery environment.

The aim with the product was to get a good acceptance from the staff at hospitals and also the patients.

Demarcation

The project did not include any proof of a working concept since that should need studies that are far beyond the limits for this project in time and recourse. The technical development and the clinical studies involved to show proof of concept and safety would require several years to be completed.

Issues identified at the start of the project

- How to adopt the design to the standardized and regulated hospital environment?
- What design will optimize the bacteriostatic effect of the device?
- What are the restrictions of the device design from a security to the patient perspective?
- What are the requirements from a medical device regulatory perspective?
- How to assure compliance? - Acceptability by the patients and hospital personnel
- What is usability in consideration to this sort of device? How will you interact with it?
- How will the design effect how suited the device is for a hospital environment

Implementation Understanding

The paramedics are the caretakers of the patients once they are enrolled at the hospital. It was therefore important to understand their work better[3], and their general problems with modern technology in hospital-related products. From the pre-study it was learned that there was an uncertainty when using equipment that was not direct and consisted of too much technology.

The focus of this project was to look at new technologies and not to the most widely used sterilization techniques today such as chlorhexidine and alcohol.

A review of the field revealed two new and promising groups of sterilization techniques, non-thermal plasma and HINS-Light(High-Intensity Narrow-Spectrum). Both of which were harmless to the patients skin.

Non-thermal plasma[4] is a modern technique of using plasma with lower effect. As the name tells the plasma is not hot which facilitates the use on human skin. The bactericidal effect is obtained from reactive species in the plasma. This technique has several good properties for the medical area, but has so far not been used that much outside the laboratories.

HINS-Light[5] is an even newer laboratory technique. It is sort of UV that emits in narrow spectra round 405 nm. The difference between the “general UV” and HINS is that the spectrum between 100-280 nm is considered more germicidal but it also makes it carcinogen[6].

A literature search in this area showed very few applications of the techniques, none based on HINS-Light and very few products, one dental[7] and some prototypes[8] with “cold plasma”. There are existing products with UV for difficult surgery’s but is mostly used to sterilize rooms[9].

It is obviously interesting to study how well these techniques can be applied in a hospital environment and how effective they are in reducing the more difficult microorganisms such as spores, multi-resistant bacteria and fungi that are considered difficult to kill[10].

Technical research

Non-thermal plasma

Beneficial[11]

- Provide contact-free and pain-free disinfection in seconds
- Alleviate pain caused by infections
- Alleviate skin irritations and reduce the risk of infection caused by scratching
- Promote faster healing
- Decontaminate/disinfect equipment, fabrics and possibly whole rooms
- Provide efficient disinfection in seconds
- Disinfection without waste products

UV(100-280nm) / HINS-Light(405nm)

Beneficial with UV[12,13]

- Treats visible environment
- Effective against a wide range of pathogens
- No chemicals or chemical pre-treatment

HINS

- Safety advantages over UV-light
- Low running costs (LED based system)

	Chlorhexidine	Non-thermal plasma	UV / HINS- Light
Time	2,5 min	5 - 10 sec	30 min / 8-14 h
Cost	8 € / per surgery	1800 € annul	10.000 € /per device

Table 1

Regulations

There are a lot of regulations for hospital environment and medical devices. (LVFS 2003:11).

The regulation divides into paragraphs:

- 1993:584 about medical devices
- MEDDEV 2.4/1

Guidelines for the classification of medical devices

(according to MEDDEV 2.4/1)

All devices must

- Meet the essential requirements irrespective of the class of the device
- Be subject to the reporting requirements under the medical device vigilance system.
- Be CE marked

This sort of devices needs an IIA classification

- No instructions for the use is needed
- Clinical data from investigation and evaluation is needed

Guidelines for CE-classifications [14]

Classifying this sort of device needs to follow several rules but the general regulation that could be useful in this stage of the development is about having a manual and that the product is marked with CE in a size not less than 5 mm in vertical height.

Evaluation

The evaluation of the techniques was processed through a Pugh-matrix(see appendix A1) where the questions where:

- **Control of sterilization**
How well the hospital knows that a well sterilization has been done
- **Usability**
Applying the method
- **Efficiency in time**
Time of sterilization a patient
- **Efficiency disinfection**
Time of bacteria killed during a time span (See table1)
- **Cost**
Cost of using the method over a long run (See table1)

- **Environmental**
Waste from using the technique
- **Over all body help**
How good the technique is for the body
- **Result**
Remaining microorganisms after the sterilization

This lead to the conclusion that the plasma technique was the better one as shown in fig. 1.

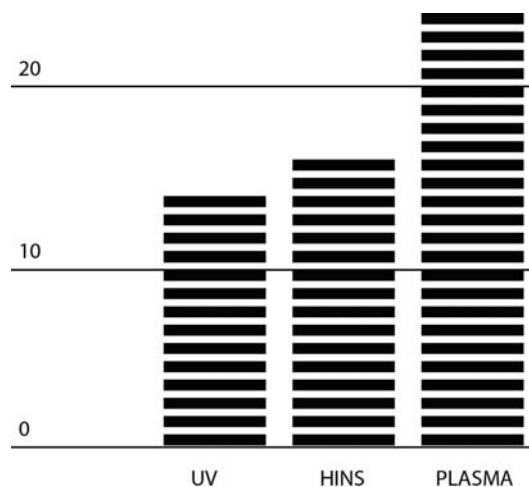


Figure 1

Interview / Observation

Patient

To get a better understanding of the hospital process a research where made with patient interviews, using a semi-structured interview technique to get an over all perspective of the process, but also get a subjective description of thoughts about there visits. This was compared to Sahlgrenska day-surgery mailings[15], how chlorhexidine[16] function and in patient interviews of handling the home sterilization.

The study gave insight to the general feelings of hospital processes and thoughts about the environment and equipment. A preparatory substrate was made out of the patient interviews that was used when visiting Mölndals hospital orthopaedic department[17] in Gothenburg.

Keywords for product: clean, intuitive, serious, light, modern

Hospital

A visit in Mölndals hospital orthopaedic department gave a good perspective of how a surgery department worked and looked like.

From what kind of patient that were visiting, how they purchase equipment, hospital colour codes(*See fig. 8*) and time perspective, room sterilization, tool cleaning, preparation, sterilization routines, the importations of draping and how unpleasant information such as gathering mucous and blood were kept from the patient.

It also gave an idea of how the equipment and tools were used in the surgery and how it was handled (cleaning, repairs, storage).

Keywords for product: understanding, cleaning, strong, and functional

Thoughts from the visit to Mölndal hospital

Reception

The reception was very small and the hall was in a direct connection with the patient rooms, one for each gender.

Patient room

The patient room contained several beds with screens in between for privacy of the patients. Everything was white and there was a window in the far side of the room, it looked very clean. From here the patient was moved to the surgery area. This area was crowded with various machines, mostly powder coated metal in light colours. In this area all personal needed to wear a hood, but during my short time spent there I could see one student who forgot.

Preparation room

There were two entrances to the surgery room from the preparation room and another directly into the hospital area. During a surgery you shouldn't enter more than if really necessary, and then only enter from the preparation room. In the preparation room there was lots of tools and machines.

Surgery

The surgery room was much bigger than preparation room and without windows, but you couldn't be more than 8 people there at the same time. The area close to the patient was marked on the floor so just the operating surgeon was close to the patient. The bed in the surgery was facing inwards and there were a lot of machines everywhere. Some of the machines that were collecting blood and mucous were placed behind the patient. The bed itself had many

settings to get it in the right position and where placed in the centre under a big lamp that was constructed not to blind the patient.

Recovery

The recovery room was more or less like the patient room with machines showing the state of the sedated patients, and there was a nurse watching monitors all the time.

Patient room

After a patient woke up he/she was moved to the patient room for a short rest.

Summary of hospital and patient research

General routines in connection to a planned surgery (See fig. 2)

1. Preparations at home prior to the surgery

Information about the planned operation will be sent to the patients' home. This information tells you what do before getting to the hospital and you can read about how you should do your home sterilization. With a home sterilization you should shower. The cleaning consists of two showers with Descutan or Hibiscrub (a chlorhexidine shampoo, purchased at the pharmacy), one the day before and one in the morning of the surgery day. For less invasive procedures (ear, nose, throat and dental procedures) the patient uses regular soap.

The patient should also remove nail polish, jewellery, piercing, contact lenses, change to clean clothing and bed linen.

Disadvantages with the process

- Patient could be unable to wash himself in a good and controlled way.
- Chlorhexidine must be in a direct contact with the body to have effect.
- Chlorhexidine has a reduced effect if the patient uses soap after treatment.
- Some patients may experience an allergic effect of the preparation.

Advantages of preparation

- Chlorhexidine has a well-established bactericidal effect
- Patient can do it at home

2. Transport to the hospital reception

- Public transportation, taxi or similar is normally used to the enrolment at the hospital.

3. Patient room

- The patient changes clothes and the nurse checks the patient's identity
- The patient is asked about the compliance to the prescribed preparations and other questions about the patients' health.
- The surgeon visit the patient to inform about the surgery
- Patient gets preparation such as drugs, blood tests, etc.
- The patient is moved to the preparation room in a bed with wheels

4. Preparation room

- Preparations before surgery such as antibiotics, blocking, drugs
- The room is sterile ventilated, and there are stricter roles in this room

5. Surgery

- Change of bed
- Change of staff
- Connected to the surgical equipment
- The body is covered with draping, cap and sheets
- The engagement region chemically sterilized with chlorhexidine.
- The patient is anesthetized if needed.
- The surgery is performed

6. Recovery room

- Monitoring of vital physiological parameters.

7. Patient room

- Information about the surgery is given and preparations for journey home are made.

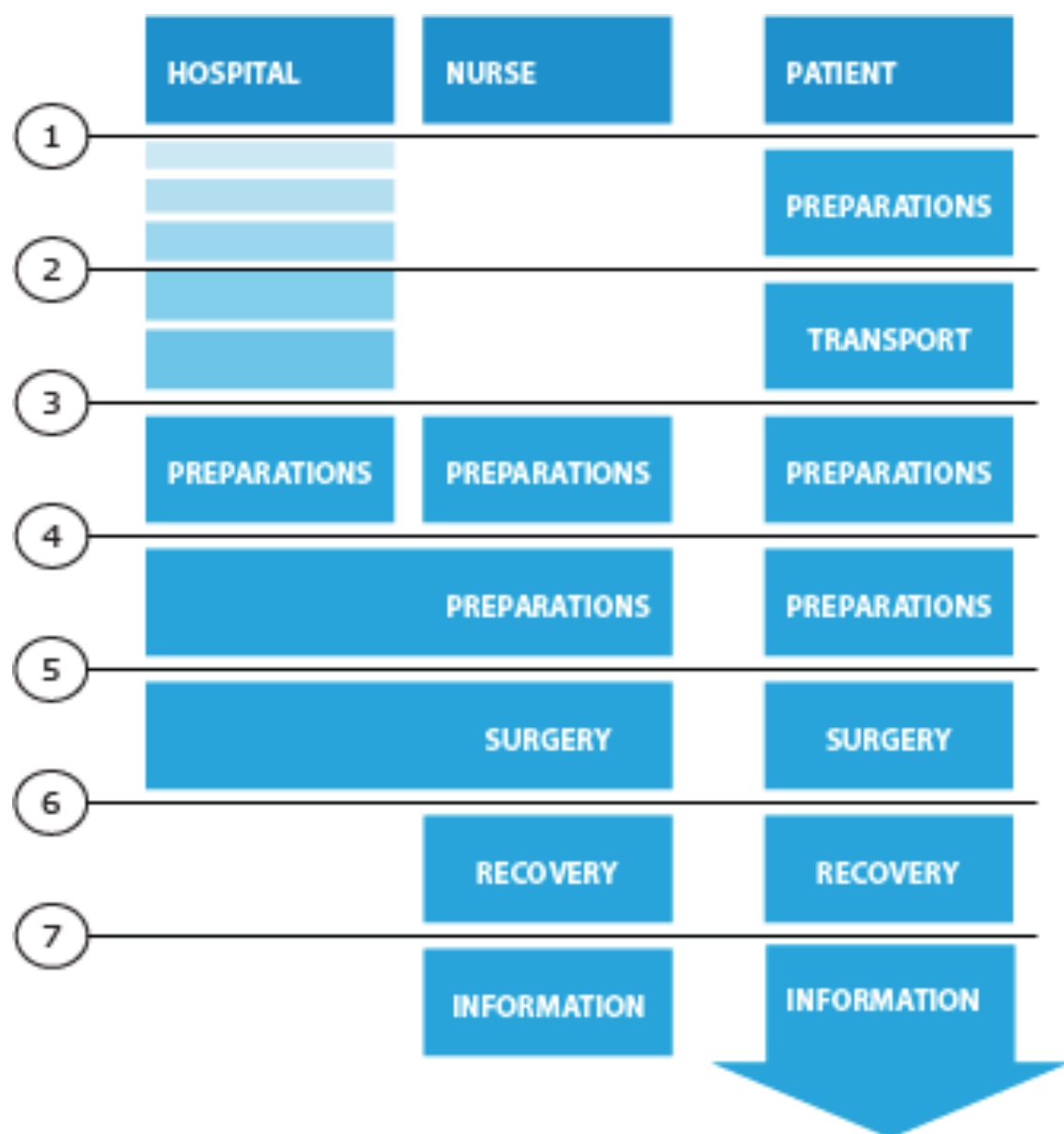


Figure 2

Synthesise

Plasma technique had to be 40 mm or less from the patient's skin to be working. The sterilization should be as close to the surgery event as possible.

Looking at the organic forms of a human body it is hard to find regularities to make standard forms of a device. If the device were to embrace the whole body by a form the patient would have to be physically in shape, which would exclude for example handicapped in wheelchair etc. Another problem is that some parts of a patient's body are sensitive and could be hard to reach (See fig. 3).

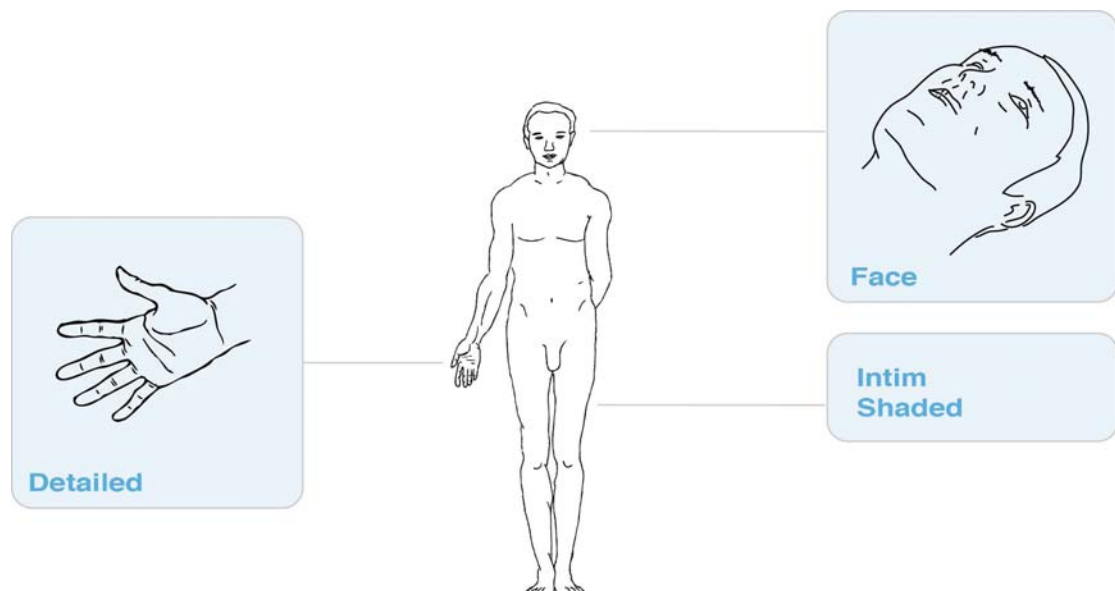


Figure 3

Concepts

From the technical restriction and looking at how a product like this could fit into the now existing surgery process a list of questions for brainstorming was made.

Question for brainstorming

- How can you cover a whole body?
- How does patient sit/lay down (how can staff help?)
- How to access difficult areas?
- How to get a relaxing feeling?
- How to get an easy handling?

The brainstorm lead to a couple of keywords that where processed in to concepts through visualizations and understanding of the patients needs.

Keywords from brainstorm: vacuum mattress, washing utensils, resilient carpets, robotics precision and 3D-Scanner

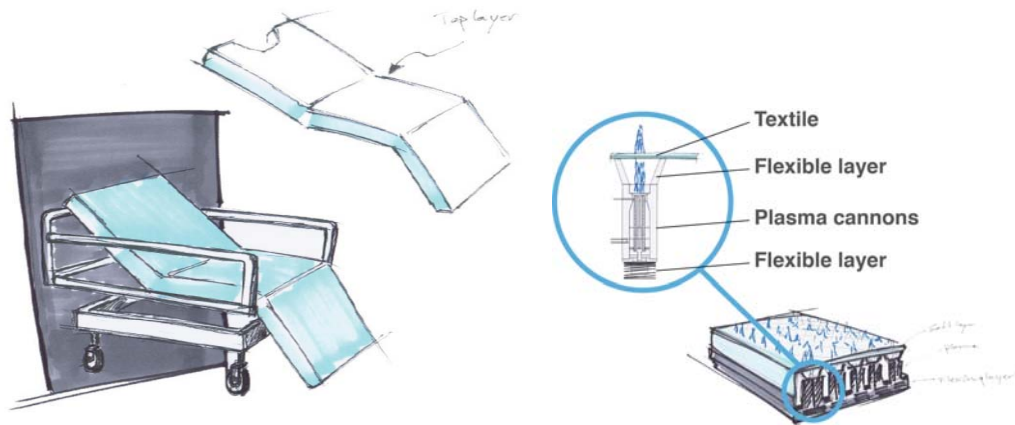


Figure 4

Concept 1

The inspiration to this concept came from the hospital vacuum mattresses and flexible nail-carpets to embrace a whole body with plasma jet canons.

The patients are supposed to sit-down in the bed and then get a covering mattress that sterilizes the upper body. Because of the flexible material in the mattress it should cover all parts of the body except the head. (See fig. 4)

+

- Soft
- Relaxing
- Covers almost all parts of the body
- Fast

-

- Could contribute to a choking feeling for the patient
- Would be considered bulky in a hospital environment
- Could be hard for the patient to get up and down from the device

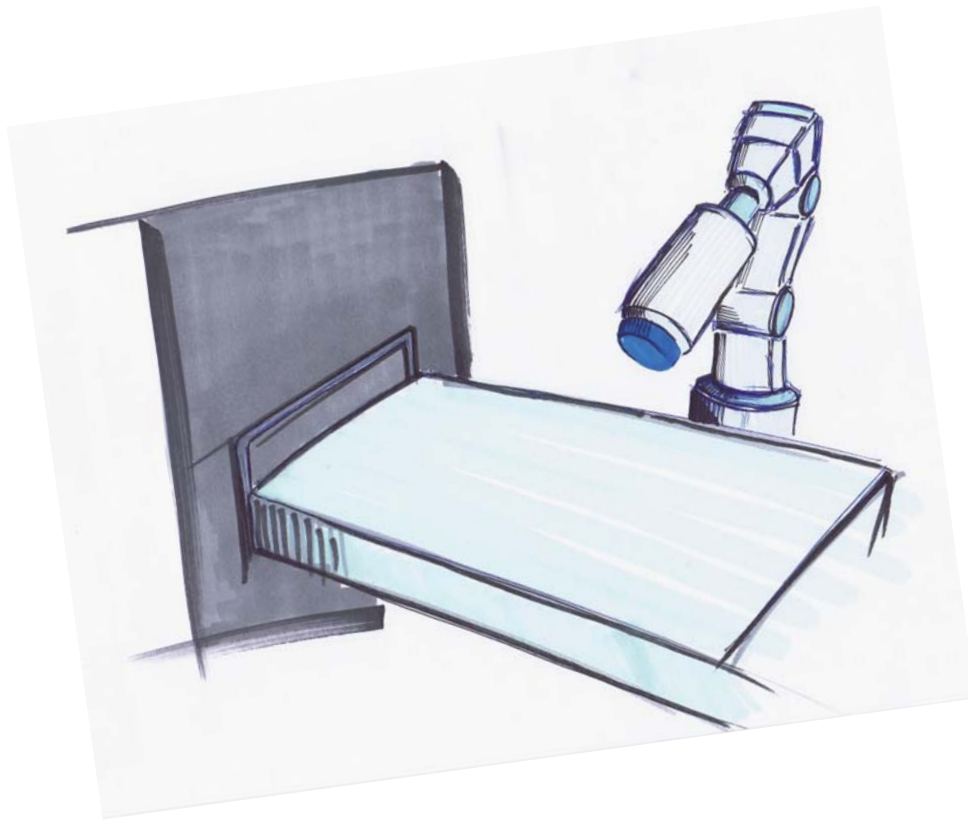


Figure 5

Concept 2

This concept builds from two industrial technologies 3D-Scanning and robotic accuracy. The 3D-scanner processes the body periodically and gives the robot with a plasma nozzle coordinates to sterilize. This makes it possible for the patient to move around and get sterilized all over the body, even in the narrow areas. (*See fig. 5*)

+

- Flexible in use
- Accuracy
- Could cover all parts of the body

-

- Could be scary for the patient and staff to use
- Would be needing a stationary placement in the hospital
- Lots of parameters to work correctly during a procedure
- Difficult to clean



Figure 6

Concept 3

The problematic involved in covering a whole body with accuracy using a handheld device lead this concept primarily to be working on local areas of the body, but with the possibility to cover all parts of the body.

The scanner is put directly against the patients skin and the patient gets a good contact with the nurse during the procedure.

The device can virtually be used anywhere in the hospital area, which makes it very practical. (See fig. 6)

+

- Relaxing
- Could cover all parts of the body
- Patient-staff contact
- Easy handling and cleaning device
- Mobility

-

- Slow to sterilize the whole body

Evaluation

During the pre-research stage important keywords that could be segmented to apply for the final product were regulations, sterilization, acceptability, usability and suitability for hospital.

Putting them in the context of the concepts and research with keywords as understanding, cleaning and hospital handling the third concept was the most suited for the assignment. But to be sure about how the concept would be functional in the hospital a HTA process was made where the concepts could be applied (*See fig. 7*).

The picture shows that the first concept gives both the user and nurse a lot of steps to process. The second concept gives less steps, but both of these concepts are stationed at a curtain place due to the size and how these operates.

The third concept has the same process steps as concept two but it has a mobility that could be useful in operating departments where it could be used in several places.

Therefore in accordance with research keyword, process understanding and the best use of the properties of plasma, concept three was chosen for further development.

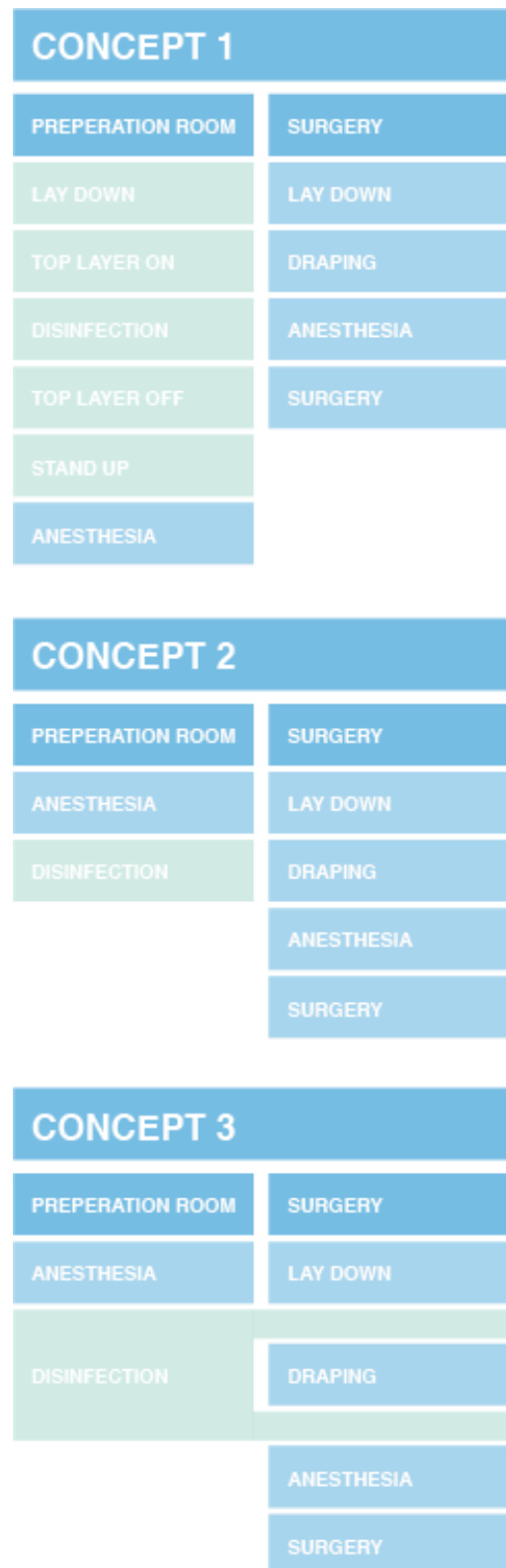


Figure 7

Result and discussion

Design process

How could the design and functionality of the device be improved and optimized? This question could be answered in many ways, but due to the lack of survey group and reference products the work focused on a hypothetical perspective where the questions of development came from the research and common product problematic[18]. From this a fishbone analysis(see Appendix A2) was made which led to three larger groups of consideration during the design process.

Functions

Technical requirement

- Has to be close to the patient
- Electricity

Sterilization requirements

- Has to be able to sterilize all parts of the body
- User has to be able to see that the device is working
- A start/stop function

Ergonomics

- Adapted to height and settings of a surgery bed
- Possible to hold with a firm grip
- Grip for left and right handed
- A grip adapted to different sizes of hands
- Possibility to change the grip for easier access
- A form that conveys a sense of how your holding the device
- Easy to move around the body
- Easy to handle the device and to follow the sterilization process
- Should feel uncomfortable for the patient, mentally or physically

Aesthetics

- Mobility and agility
- Function
- Modern
- A rapid process
- Precision
- A good grip
- Simple
- Sterile and clean
- Comfortable
- Sustainable
- A part of the appliances in the hospital family

Direction of the design

In the hospital environment the design of the apparatus varies from functionalism to more aesthetics depending on the target buyer group, from a strictly hospital product to a private operator.

The design intentions were aimed to a level where it was as patient friendly as possible with a recognitive design, but still had the functionalism that the hospital staff wanted. Throughout the design process focus with this in mind the keywords and blue as accent colour fitted the hospital environment (See fig. 8).

Form keywords: *Strong, Precision, Clean, Streamline, Grip, Smooth, Simple, Light and that it's suited for the hospital environment*



Figure 8

Ergonomic

When forming the handle of the device I found the restriction to be in the interface between the patient and nurse. Looking at a common surgery bed there is a lot of different angles a patient can be positioned in (See fig 9). There is also different heights from where the nurse will be sterilizing.



Figure 9

Mock-ups with clay and common tools were made to find an angle and handle that could be considered to be consistent with how a sterilizing would be made. Inspiring tools flashlight, garden, shower nozzle and more. See visualizing process (fig. 10).



Figure 10

Nozzle design

Draping of the patient is essential, in order to reduce risk of self-contamination. This means that the patient has a small area of skin to be sterilized. The nozzle on the product that is touching this area was therefore softened. The front was rounded to easier get to the narrow areas without harming the patient. And the nozzle shape was made squared with a size that permitted easier visual mapping of the sterilization area during the process (See fig. 11,12).

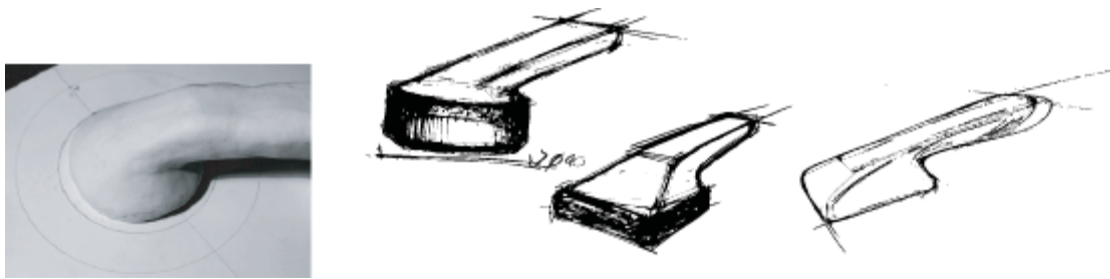
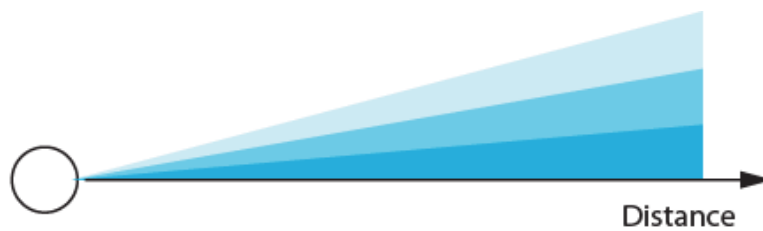


Figure 11



Easy eye rotation (15 degrees)
Limit for word recognition (5 - 10 degrees)

Figure 12

Product indications

An important part of the device is that it has a fully understandable indicator system that gives the user a feedback. Indication gives the user and patient a reassurance that the device is on and that it is working. The device should show the user that the plasma is close enough to the patient and also indicate a full sterilization cycle. (See *process of indicator development fig. 13*)

The most cognitive placement of an indication where to put it by the plasma. This would show as a strengthen light to the plasma. To indicate that the plasma is not close enough to the patient the LED-light should stop emitting light. To show the sterilization cycle a light indicator could be used, but it could also be perceived as a stressful indicator and the user have to focus on it as well. Therefore a sound indicator with a tone that tells the user when the process is sufficient was chosen.

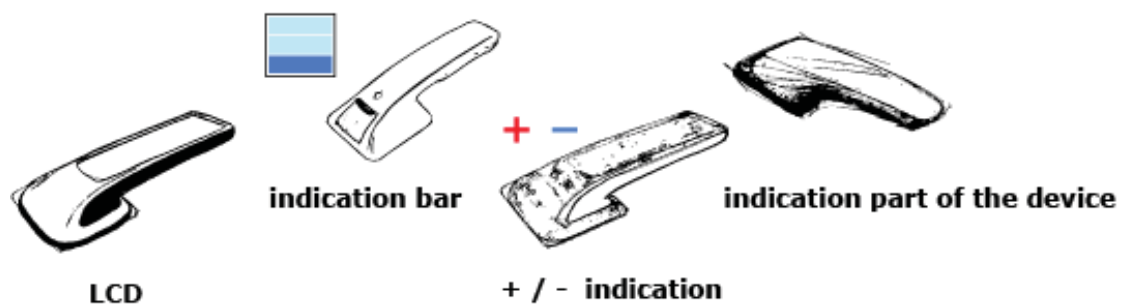


Figure 13

Grip

Hand held tools in hospitals differ according to area of use. Patient S should have a precise and powerful grip, independent of what body part to be sterilized.(fig. 14)

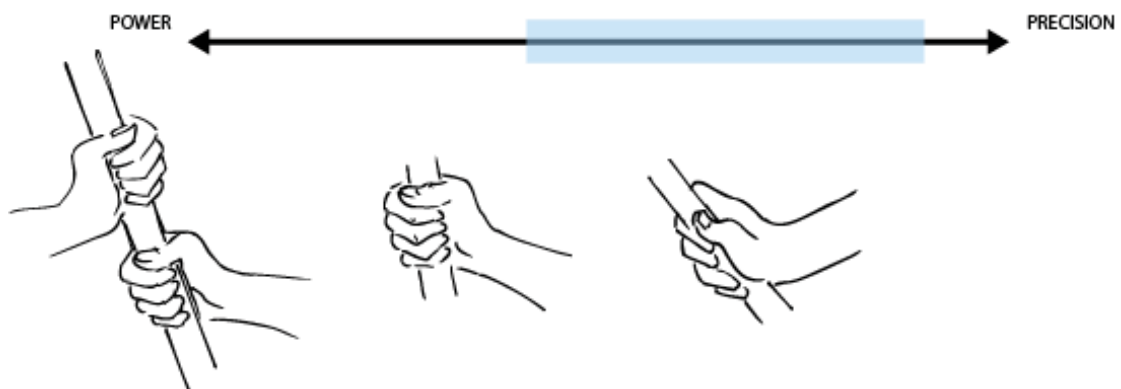


Figure 14

It should be possible to handle with different hand shapes/size. I therefore found it useful to work with clay(*fig. 15*) and anthropological measurements[19], focusing on the index finger and a precision grip with a smooth transition to a better grip. I also worked with finding tactile points of the handle topside and ends of grip.



Figure 15

Start / Stop

To activate the product it requires a start button, this also prevents the product from getting active at the wrong time. The user may also want to turn it off according to key logistics with on/off buttons.

The product is meant to be used with one hand and is designed to suit both right and left-handed. The button is therefore placed on top near the thumb instead of at the end of the handle.

The exact placement of the button was measured using a mock-up to get a comfortable distant(*fig. 16*). The size of the button was also measured, to get right preparations and not cover a larger area then necessary.

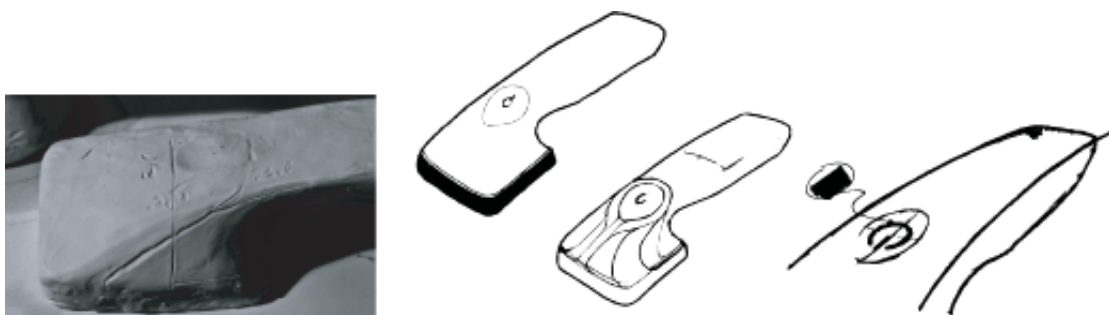


Figure 16

Mobility

Movement and agility is two of the stronger properties of the unit. A cord in this environment could be a source of infection and had then to be covered in a disposable plastic. Another possibility would be to power the unit with batteries, which seemed to be possible.

A charging connector to this unit could also be a source of infection so my final solution was to work with induction charging in a connector free charging system.

Refine the design with CAD

After the main definition of the product had been worked out (fig. 17) the work in CAD for better definitions of the organic forms was started (fig. 18). The colouring of the device was defined according to the hospital colour codes, with a blue for clean and different glossiness for a clean look.

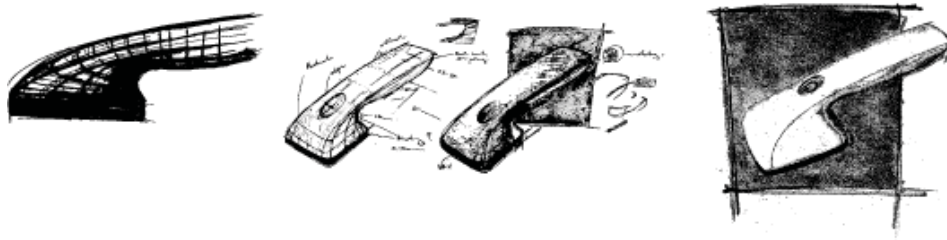


Figure 17

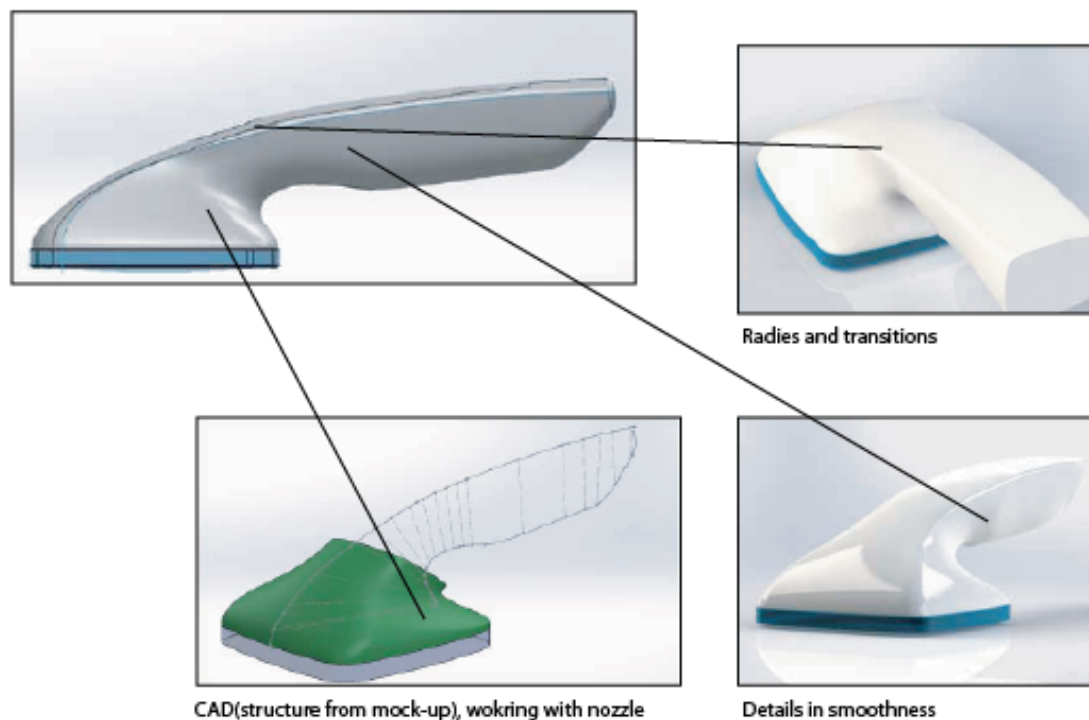


Figure 18

Product description

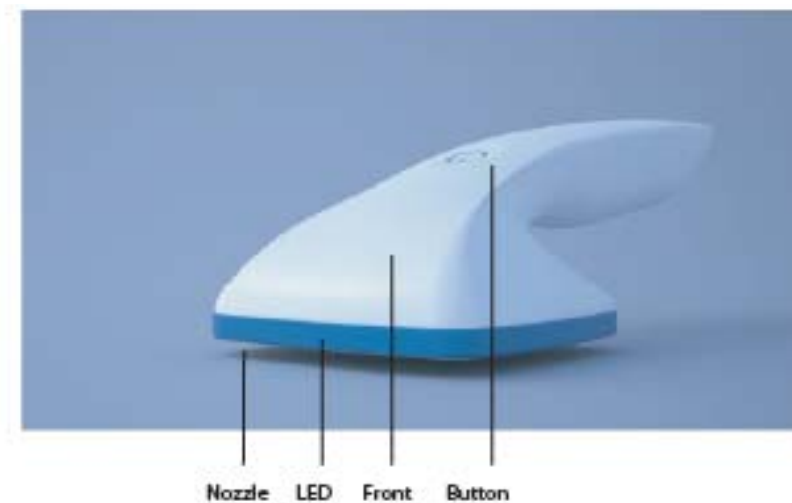


Figure 19

Nozzle

Restricted by the LED as the delicate tool, this surface irradiates plasma when on from a slightly convex surface to prevent nozzle sticking to skin.(fig. 19)

LED

A blue shiny rail outlines the nozzle and makes a strict divider between handle and active plasma. When the unit is active LED emits blue light to strengthen indication of the active plasma. The LED is slightly bigger than the body and therefore emit a hint of light upwards for better perception from all angles. The LED is rounded from all sides for a soft patient approach.(fig. 19)

Front

Top comes with a flow down to the nozzle/LED and connects the handle and plasma source in a soft but defined way.(fig. 19)

Button

The button is 1 mm circular deep with blue light from on/off symbol when on, and has sharp tactile outline. It is fully closed from bacteria or spores to enter.(fig. 19)

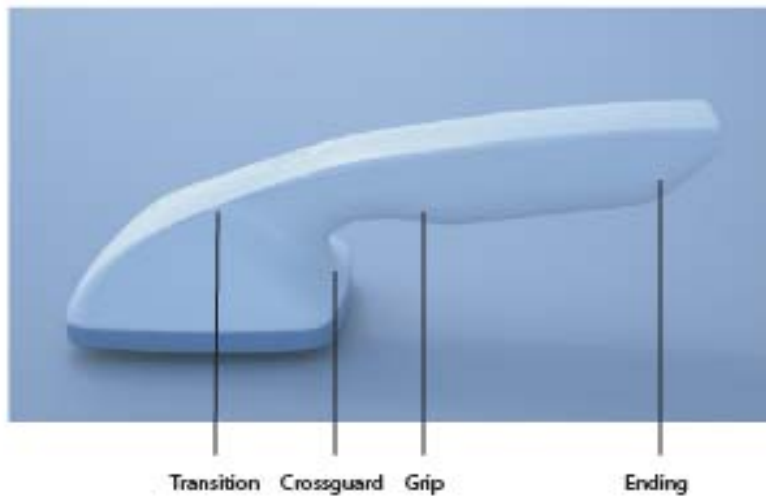


Figure 20

Transition

A soft transition divides the handle and front. The transition works as a part of tactile outline from the top to feel that this is the end.(fig.20)

Crossgard

Tightens the index finger and prevent it to slide on to the patient. This gives the user a closer connection to the patient and the area to be sterilized for better precision.(fig.20)

Grip

Both crossgard and grip is sized for several hand shapes with a soft rounding according to anthropological measurements. Grip consists of a tight area in the front for a precision grip and wider on to the middle, which creates a more powerfull grip.(fig.20)

Ending

Ending is a part of the grip that gives the user a sense of that there is no more handle to hold.(fig.21)

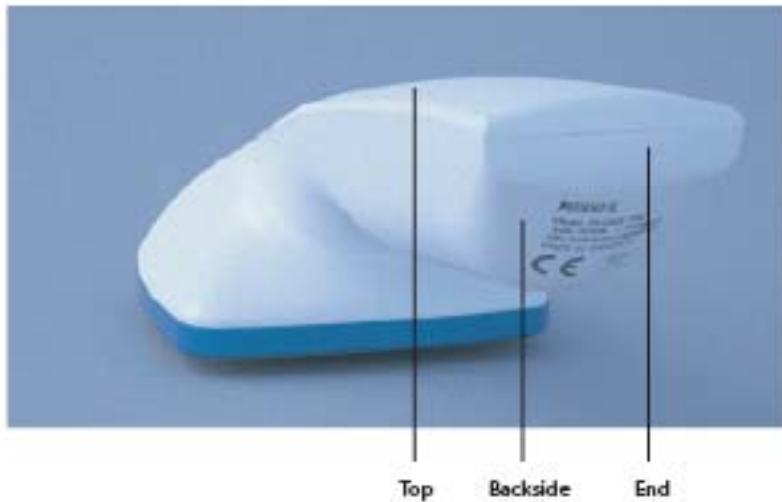


Figure 21

Top

Defined with a slightly rounder edge, that is easy to follow with fingers. The upside which is slightly curative giving the surface strength and softens the product. Upside is slightly bent giving the hand different angles depending on where you're holding and also helps with the products direction.(fig.21)

Backside

Backside has the properties of fitting a CE-certification mark that is necessary for all electronic equipment.(fig.21)

End

A strict end for the top defined by the split-line that connects with the flow and direction of the unit.

Charger for Patient S

This device should load Patient S with induction charging. For it to be possible the unit has to be in direct contact with the surface of the charger.

Functions

- Easy connecting and disconnecting Patient S
- Stations Patient S
- Outside of surgery it has to be fully protected

Aesthetics

- Silent (don't indicate information)
- Stationary
- Stable
- Mobile when disconnected
- Clean
- Aesthetics connective with Patient S

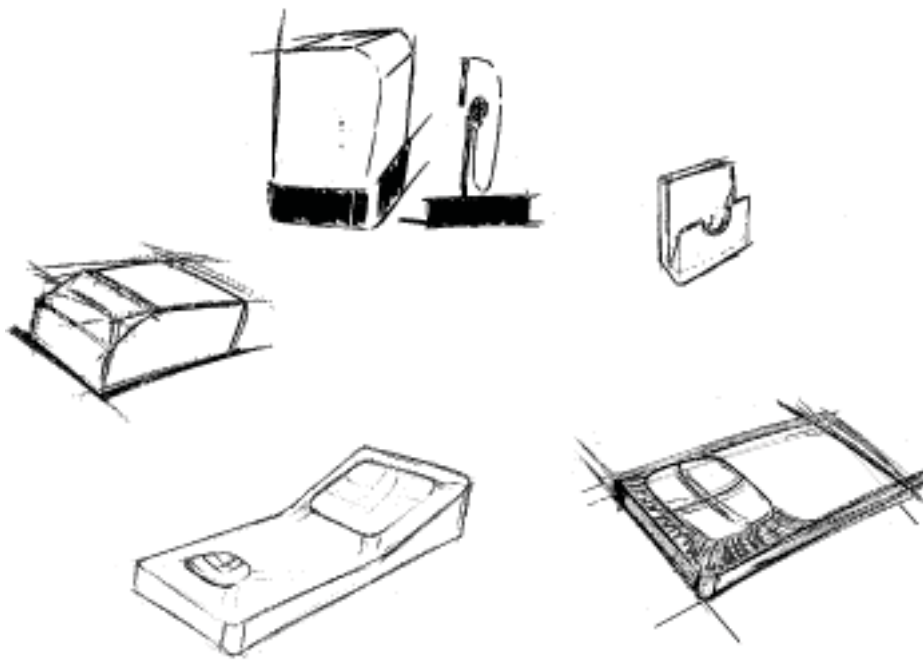


Figure 22 (Concept process)

Properties of charger

When patient S is resting in the charger the nozzle of the device is protected against outer damaging, it also makes the back of the device lean against the indication active surface for a better connection and charging.(fig. 23)

- Slightly tilted backwards for easy picking up of Patient S
- Distances so it stands still with out wobbling
- Protects the nozzle of Patient S
- Easy to clean
- Short cable (useful when packing)
- Aesthetics is more strict then Patient S to communicate a stationary unit
- The charger is silent (not showing any indications), fully charged unit is indicated with a flashing light from the button of Patient S.

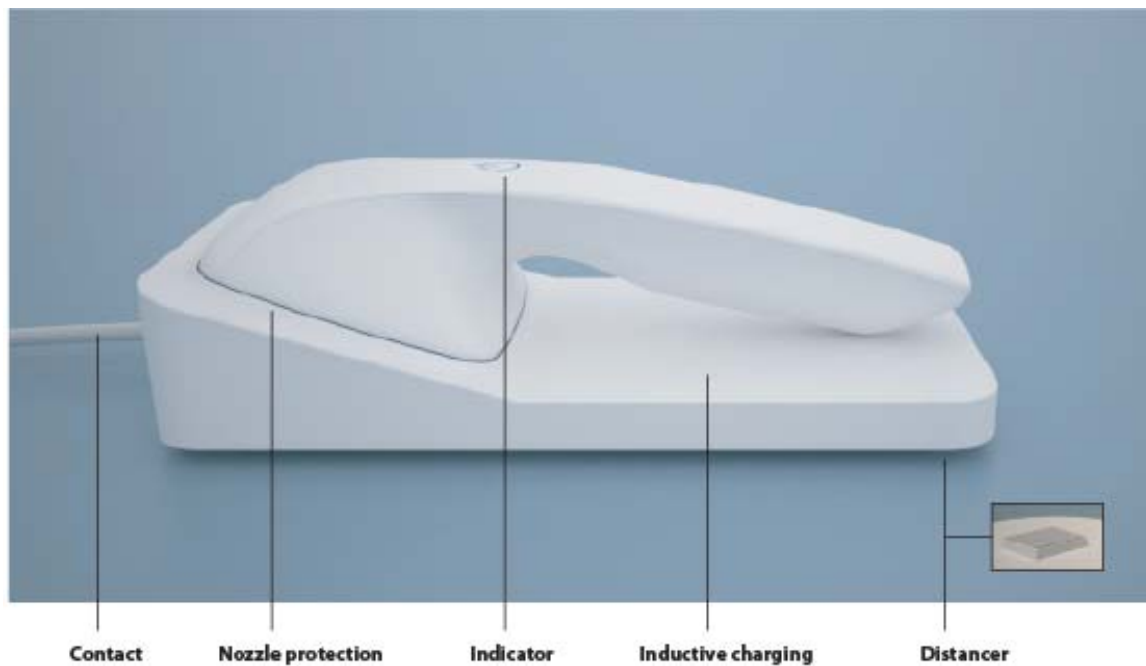


Figure 23

Using the device

The device is protected in a case and can be placed anywhere in the hospital.

To begin using Patient S, open the case and clean the unit with alcohol (standard procedure before placing the devices in to the surgery). The case should be left outside of the surgery or in the preparation room connected to the surgery.

Set up the charger with the device in the surgery and connect it to electricity (location in the surgery is optional as the rooms may vary). The unit is now charging and will flash from its button when it is fully charged. It is then ready for use. When the patient has arrived and everything is in place with draping and connected to all devices you start the sterilization with Patient S. The draping makes the engagement area fully protected from the rest of the patients' body so sterilization is just needed here.



Figure 24

The device is placed against the area to be sterilized. The unit is activated when held closer than 40 mm to the patient, and then you press the on/off button. The unit will then emit plasma and simultaneously light up around the nozzle and from the on/off button with a blue light(*fig. 24*). The patient will probably only feel the unit lying against the skin. Both user and patient can easily follow the sterilization process from all angles and see that it is active(*fig. 25*).

After 5 seconds, the device emits a tone to indicate that sterilization is sufficient and it can then be moved to the next area if needed. It does not matter if the area is irradiated longer (the plasma is harmless). However, one should restart the process of irradiation if interrupted to certify a complete



Figure 25

sterilization of the area. Local air temperature raises 5 degrees during sterilization. To get into narrow areas, the handgrip can easily be changed and the thumb loosens from the button for better ergonomics. The plasma has good penetration of the tight areas such as cracks and it even penetrates textiles. This procedure should be much quicker than a standard procedure with chlorhexidine. It doesn't leave any waste, doesn't give any skin irritation and involves no liquids, which is good for the patient, nurse and the hospital.

Since the device is handled with one hand the other hand can be used to move the patient during process if necessary. When sterilization is complete, the device is disabled by moving it from the body or by pressing the button. The device could then be placed back in its charging stand.

The unit can be left in its charging stand between operations, but must of course be cleaned like any other equipment that are to be used during a procedure in order to reduce the risk of spreading infections.



Figure 26

Beneficial properties of this device(fig. 26) are:

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> - Mobile - Easy to clean - Works for both hands - No waste - Works in different humidity - No skin irritation - Works with all patients | <ul style="list-style-type: none"> - Informative - Works through textile - Fungicidal effect - Virucidal effect - Bactericidal effect - Reduction of spores - Wound healing effect |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Manual



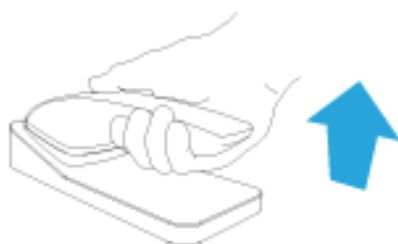
Patient S should be stored inside the case when not used



Clean both units with alcohol before usage



- 1) Connect the charger with the unit to electricity *LED at the top of the unit will flash when it is full charged*



- 2) Lift the handle to release the device from the charger



To activate the plasma hold the device to the patient's skin or a maximum of 40 mm from and press the button. The unit will then start, this is indicated by the stripe around the nozzle and the button that will light up in blue.

To finish press the button again or lift the unit more than 40 mm from the patient. The light will then turn off and the unit is off



The sterilization of the area takes 5 seconds and then you hear a tone. One can then move the nozzle to the next area or stop.

Thumb do not have to be on the button throughout the process, this makes it easier get everywhere on the patient. Unit will emit a blue light throughout use.

Discussion

To summarize, in a project like this there are several things that need to be done before a final product can be presented. Apart from the physical design of the device the technique itself has to be further developed to fit the technical specifications and furthermore it has to be tested for proof of the concept in various clinical studies to verify that it is safe and efficacious. Such a development program would involve different expertise and would probably take years to complete, which obviously is not within the time frame of this work.

Throughout the project a lot of time was spent on research in order to get an understanding of the healthcare sector and the special requirements that are involved with the use of medical devices.

This sort of understanding could also be seen in a different perspective from a designers' angle towards the hospital process and the functions of a sterilization process that can be improved.

The aims for the product are still the same as initially, but through understanding during the project I could see greater functionality for this kind of product in different fields such as in ambulances and fieldwork. With these criteria the design of the product would probably have taken a different direction. This project could still work as a ground for further studies towards this. Economically and environmentally over a longer time period this concept is probably a superior solution for sterilization than the techniques used today. This must be verified in studies where the different techniques are compared head to head.

The initial interpretation and hypotheses of a final product was more directed towards a stationary product and the room perspective, but understanding the patient and the differences in hospitals it was hard to see how it could fit in and therefore a mobile solution was chosen.

The layout of the product was left quite restricted because of regulations and adaptation to the environment. In spite of that the design of the product could still be made interesting besides the necessary function. Ergonomic and inter-facial details are a big part of this product and therefore have set the outlines of the form with the hospital as a reference. Further evaluation of the design would be needed to get an approval or disapproval from the staff. The process so far could be seen as normative and the product is not fully developed which reflects the rather vague comments from the staff.

Questions about the form of the product and especially the logistics and placement of the button were part of examination when the project was presented. These things could be seen as subjectively designed and could be changed in a further development. A further development of the device would also involve reference groups.

However, at this stage of the development process and based on the work done the position of the button seems optimal given the scenario of sterilizing different parts of the a body. Ergonomically the product should fit several kinds of hands and gripping. The design could be seen as subjective but is evaluated from anthropological measurements. The prototype gives a natural grip and self-explanatory handling and that was the aim. It also comes natural how the product is placed in the charger without further explanations.

In conclusion, this project involved a long learning process to get acquainted with the special conditions and requirements for medical devices. A model of Patient S has been developed based on the knowledge. To become a final product the technique has to be further developed and the concept tested in clinical studies.

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Appendix

A1 Pugh-Matrix

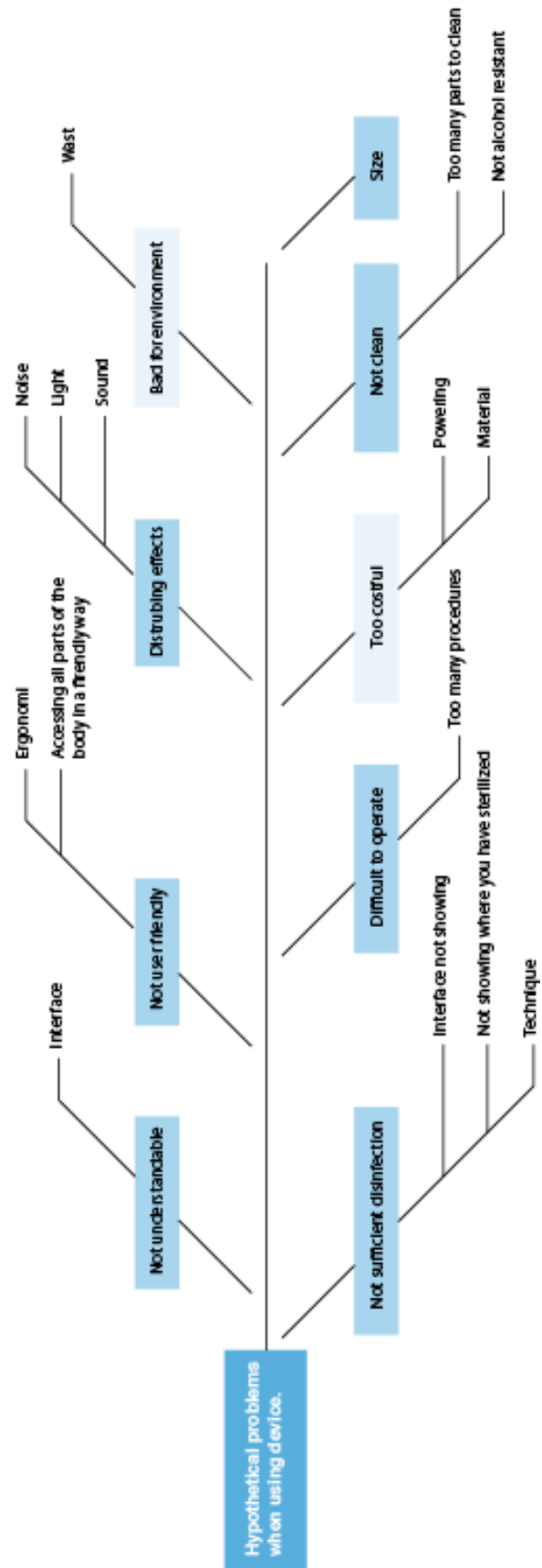
A2 Fishbone analysis

A3 Renderings

CRITERIA	IMPORTAINS	HIBISCRUB(CURRENT)	UV	UV(HINS)	Non-Thermal plasma
Patient controll	5	0	1	1	1
Usability	3	0	1	1	1
Effincansy (time)	4	0	1	-1	1
Effincansy (dinsinfection)	5	0	-1	-1	0/1
Cost	3	0	1	1	1
Environmetn	4	0	1	1	1
Body help	5	0	-1	1	1
Resault(Killed bacteria on the body)	5	0	1	1	0/1
			14	16	24/34

A1 Pugh-Matrix

A2 Fishbone analysis



A3 Rendering

